## PREMIER DIRECTING.

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July 27, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204



RE: 21 U.S.C. Section 343(r)(6) Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Ear-Health Support Formula, a dietary supplement. Premier Direct, Inc. is a manufacturer of Ear-Health Support Formula.

## Statements Being Made in the Labeling of Ear-Health Support Formula

(1) Traditional Chinese herbalists believe that the sense of hearing and ear health is promoted by nourishing the kidneys and blood. Ear-Health Support Formula is designed to do just that - help nourish and tonify the liver and kidneys. Additionally, it's designed to have an influence on the central nervous system, as well as help tonify the blood.

To the best of my knowledge, and based upon information and belief present at the time of executing this notice, I certify that this information is accurate and complete and Premier Direct, Inc. possesses substantiation that the statements are truthful and not misleading.

John Skund VI

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